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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,560	05/19/2000	JADWIGA CHROBOCZEK	3339-422	2330

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,560

Applicant(s)

CHROBOCZEK ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Applicant's election with traverse of the peptide vector comprising a segment of an NLS sequence including SEQ ID NO:2 in which X_0 is an alanine, a hydrophobic sequence consisting of SEQ ID NO:7 in which X_1 represents SEQ ID NO:10 and X_2 represents SEQ ID NO:16 and a polymeric sequence of basic amino acids in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the claimed alternatives share a significant structural element (X_1 -[F(D/N)PVYPY]- X_2) which is distinct from the prior art. This is not found persuasive because the recited structural element is not distinct from the prior art. For example, the recited structural element is disclosed in Signas et al., J. Virol., 1985, pp. 672-678, see Fig. 2; Kajon et al., Virology, 1996, Vol. 215, pp. 190-196, see Fig. 4 and WO 97/18317 (Chroboczek et al., published 5/22/97, see pp. 22-23 and SEQ ID NO:s 5-6). Therefore, since the significant structural element recited by applicants is not distinct from the prior art, the restriction as recited in the Office Action mailed 7/2/02 is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim 4 and the peptide vectors containing the non-elected sequences are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction

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(election) requirement in Paper No. 15. It is noted that claim 4 recites a polymeric sequence of polymeric amines (a non-elected embodiment).

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-6, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chroboczek et al. (Cited by applicants).

Applicants claim a peptide vector (transfection vector) for transfecting a chemical substance (which can be nucleic acids, proteins, pharmacologically active substances, etc.) comprising a NLS sequence (AKRAR) and the sequence LSTSFNPVYPYEDS and a polymeric sequence of basic amino acids (10-50 residues of lysine, arginine or ornithine), wherein the NLS is at the N-terminal end and the polymeric sequence is at the C-terminal end of the peptide vector.

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Applicants also claim a transfection vector wherein the chemical substance is a nucleic acid and the transfecting peptide/nucleic acid ratio is between 0.3:1 up to 6:1. Applicants also claim compositions comprising the recited peptide vector and compounds such as polyols, antiseptic agents, etc.

Chroboczek et al. (WO 97/18317, published 5/22/97, see whole document, particularly pp. 6 and 22-23, Examples 3-4 and SEQ ID NO:s 5-6) teaches a peptide vector for transferring a chemical substance (such as a nucleic acid), consisting of the exact sequences claimed by applicants, wherein the peptide vector comprises 20 lysine residues at the C-terminus of the peptide and the NLS sequence is at the N-terminus. Chroboczek et al. also recite a ratio of the transfecting peptide to the nucleic acid of 0.3/1 (5µg peptide vector to 1.5µg DNA, see p. 23) and recite compositions of the peptide vector and components such as antiseptic agents and polyols. Therefore, Chroboczek et al. teaches the claimed invention.

It is noted that while the WO 97/18317 document is in French, said WO document served as the basis for the U.S. national phase application 09/068,650 (filed by the same inventors as in the instant application) which later issued as U.S. Patent 6,083,720. The English translation of said WO document in that application was relied upon in this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1-2 (and dependent claims) recites the broad recitation of a sequence of at most 43 amino acids, and the claim also recites smaller amino acid sequences (using the language "in particular" or "preferably") which is the narrower statement of the range/limitation.

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Claims 1-2 and 10 are vague in that applicants appear to recite the peptide vector as a composition of the substance(s) bound to said peptide vector and "...at least one transfecting peptide which comprises..." It is therefore unclear what the term "peptide vector" encompasses. Does it encompass a composition of matter comprising whatever substances are to be transfected into the cell and the transfecting peptide vector or does the term refer only to the peptide portion of the peptide vector?

Claims 1-2 are vague because said claims recite multiple uses for the claimed peptide vectors. In line 1 of each claim, the vectors are "...for transfecting a chemical substance..." while in the last line of the claims the peptide vectors are "for use as a medicament". It is also noted that intended use language in composition claims generally carries no patentable weight and should be deleted.

Claims 3, 5-9 are vague because there is no antecedent basis in claims 1-2 for the term "transfection vector".

NOTE:

Proper claim construction requires that claims begin with an article such as "A" or "The". Redrafting the claims to meet this requirement is necessary.

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The correct filing date for this application is May 19, 2000

Claims 7 and 9 are free of the prior art. With regard to claim 7, there is no motivation to combine the peptide vector disclosed in the Chroboczek et al. reference with a targeting ligand. With regard to claim 9, there is no teaching to transfect eukaryotic cells with the claimed peptide vector **at room temperature**.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
November 17, 2002

DAVID GUZO
PRIMARY EXAMINER
